K100546

510(k) Summary

JUN 23 2010

Submitted by:	Parker Medical, Inc. 9457 S. University Blvd., #331 Highlands Ranch, CO 80126
Contact Person	Lewis Ward L.W. Ward and Associates, Inc. 4655 Kirkwood Court Boulder, CO 80301
Date Prepared:	February 8, 2010
Product:	Trade Name: Parker Flex-Tip Tracheal Tube Common Name: Tracheal Tube (also, Endotracheal Tube)
Classification Name:	Tube, Tracheal (w/wo connector)
Intended Use:	Tracheal tube designed for oral and nasal intubation and indicated for airway management
Technological Characteristics:	Sterile, single-use device for use in anesthesia and emergent and respiratory care. Center-beveled, flexible, curved, slightly rounded, tapered distal tip. Curved and preformed (shaped) tube configurations. Two facing Murphy eyes flanking the bevel. Polyvinyl chloride material with a barium sulfate filled stripe along the length of the device.
Substantial Equivalence:	The Parker Flex-Tip Nasal Tracheal Tube is an expanded Indication for Use to the Parker Flex-Tip Tracheal Tube cleared under K984528 for oral intubations.
Test Data:	Independent clinical testing of the Parker Flex-Tip Tracheal Tube demonstrates that it significantly minimizes and prevents the nasal trauma and bleeding which commonly occur in nasal intubations performed with comparable, commercially available tracheal tubes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 21 2012

Parker Medical, Incorporated
C/O Mr. Lewis Ward
Consultant to Parker Medical, Incorporated
L.W. Ward and Associates, Incorporated
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K100546
Trade/Device Name: Parker Medical Nasal/Oral Flex-Tip Tracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: May 13, 2010
Received: May 17, 2010

Dear Mr. Ward:

This letter corrects our substantially equivalent letter of June 3, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Parker Medical Nasal/Oral Flex-Tip Tracheal Tube

Indications for Use:

Tracheal tube designed for oral and nasal intubation and indicated for airway management.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100546